

AZRACK, J.

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U.S. DISTRICT COURT E.D.N.Y.

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BROOKLYN OFFICE

TISCIONE, M.J.

ALB:EEA
F. #2016R01511

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK

----- X

UNITED STATES OF AMERICA

- against -

SONIA PALERMO,

Defendant.

----- X

THE GRAND JURY CHARGES:

INDICTMENT

CR. 20-00077

(T. 18, U.S.C., §§ 371, 982(a)(7),
982(b)(1), 1028A(a)(1), 1028A(b),
1028A(c)(5), 1349, 2 and 3551 et seq.;
T. 21, U.S.C., § 853(p))

INTRODUCTION

At all times relevant to this Indictment, unless otherwise indicated:

I. The Defendant and Relevant Entities

1. Insys Therapeutics, Inc. ("Insys") was a pharmaceutical company incorporated in Delaware and headquartered in Chandler, Arizona.

2. The defendant SONIA PALERMO, a resident of Long Island, New York, was employed by Insys as a sales representative from in or about February 2012 until August 2016.

3. Practitioner #1, an individual whose identity is known to the Grand Jury, was a licensed healthcare provider on Long Island, New York. In or about 2012, Practitioner #1 became a speaker for Insys.

II. Background

A. Subsys

4. Every manufacturer of a new drug was required to obtain approval from the United States Food and Drug Administration (“FDA”) through a new drug application (“NDA”) before introducing a new drug into interstate commerce, unless subject to an exemption not applicable here. To obtain approval of a NDA, the manufacturer had to demonstrate to the FDA that the new drug was safe and effective for its intended uses. Labeling on the drug also had to be truthful, accurate and not misleading.

5. On or about March 4, 2011, Insys submitted a NDA to the FDA seeking approval of its fentanyl sublingual spray, known as Subsys. Fentanyl was a synthetic opioid that was classified as a Schedule II controlled substance under the Controlled Substances Act, meaning that it had a high potential for abuse. Fentanyl was approximately 50 to 100 times more potent than morphine.

6. The FDA approved Subsys in or about January 2012 for the management of breakthrough pain in patients with cancer, 18 years of age or older, who were already receiving and who were already tolerant to opioid therapy for their underlying persistent cancer pain. The label for Subsys warned that the drug posed risks of misuse, abuse, addiction, overdose and serious complications due to medication errors. Explicit warnings on the Subsys label included that, as an opioid agonist, the drug could be abused in a manner similar to other opioid agonists, legal or illicit.

7. Subsys was sold in five dosage strengths, ranging from 100 micrograms to 1,600 micrograms. The Subsys label instructed that “[t]he initial dose of Subsys to treat breakthrough cancer pain is always 100 [micrograms].” A higher dose of

Subsys was generally more expensive, and thus was more profitable for Insys. Depending on the dosage and number of units prescribed, a prescription for Subsys typically cost thousands of dollars each month.

8. Insys hired the defendant SONIA PALERMO as a sales representative in or about February 2012. Her duties included calling on licensed health care providers on Long Island to persuade them to prescribe the drug Subsys.

9. Licensed healthcare providers who were registered with the Drug Enforcement Administration (“DEA”) and able to prescribe opioids in the usual course of professional practice for a legitimate medical purpose owed a fiduciary duty to their patients to refrain from accepting or agreeing to accept any bribes or kickbacks in exchange for prescribing any drug.

10. Practitioner #1 was registered with the DEA to prescribe opioids in the usual course of professional practice for legitimate medical purposes. Practitioner #1 was associated with Insys and conspired with the defendant SONIA PALERMO, and other persons and entities known and unknown to the Grand Jury, to engage in various criminal activities as described below.

B. The Medicare Program

11. The Medicare Program (“Medicare”) was a federal health care program providing benefits to persons who were at least 65 years old or disabled. Medicare was administered by the Centers for Medicare and Medicaid Services (“CMS”), a federal agency under the United States Department of Health and Human Services. Individuals who received benefits under Medicare were referred to as Medicare “beneficiaries.”

12. Medicare was subdivided into multiple parts. Prescription drug coverage was provided through Medicare Part D, which covered the costs of most prescription drugs for Medicare beneficiaries. Part D of the Medicare program was enacted as part of the Medicare Prescription Drug, Improvement and Modernization Act of 2003.

13. Medicare Part D was administered by private insurance plans known as “Plan Sponsors,” each of which dictated the specific drugs it would cover and how much it would pay for those medications. Medicare Part D subsidized the costs of prescription drugs by prospectively paying Plan Sponsors monthly payments to provide Medicare-covered benefits to Medicare beneficiaries.

14. Each Plan Sponsor approved payment for Subsys that was prescribed to a Medicare patient only if certain criteria were met, including: (i) the patient had a diagnosis of cancer; (ii) the use of Subsys was for breakthrough cancer pain; and (iii) that other strong-acting narcotic pain relievers had been tried and had been ineffective, not tolerated or contraindicated.

15. Medicare and Plan Sponsors were “health care benefit programs” as defined by Title 18, United States Code, Section 24(b).

C. The Fraudulent Scheme

16. In or about and between March 2012 and August 2016, Insys created, operated and funded a marketing program (the “Speaker Program”), purportedly to increase brand awareness using peer-to-peer educational lunches and dinners (the “Events”). Insys required its sales representatives to recruit licensed healthcare providers to provide educational presentations to other licensed healthcare providers regarding the use of Subsys for the treatment of breakthrough cancer pain in opioid-tolerant patients. In exchange for

speaking to other prescribers about Subsys, Insys agreed to pay each speaker a fee, also referred to as an “honorarium,” for each Event.

17. The Speaker Program had three tiers: Local, Regional and National. At the Local Speaker level, speakers received approximately \$1,000-1,200 per Event, plus an additional \$800 if they had another speaking engagement the same day. Regional speakers received approximately \$1,600-2,200 per Event, plus an additional amount for a second Event the same day. At the National Speaker level, Insys paid physicians approximately \$3,000 per Event, plus an additional amount if the speaker had another Event the same day. Speakers were required to sign written agreements with Insys that, among other things, required them to attend organized training sessions and use slide presentations about Subsys during Events.

18. As discussed below, in truth, the defendant SONIA PALERMO and Insys, together with others, used the Speaker Program to reward licensed healthcare providers for prescribing Subsys and to induce them to prescribe larger volumes of Subsys. Insys executives instructed sales representatives to focus their time and resources on a few select doctors and provide them with lucrative honoraria for Events and other benefits.

19. Frequently, aside from the defendant SONIA PALERMO and the purported speaker, there were no licensed health care providers with prescribing authority at the Events. PALERMO forged the signatures of licensed healthcare providers, entering state medical license numbers, National Provider Identifiers and practice addresses on the sign-in forms, to make it appear as though the Events were legitimate educational programs when in fact they were simply a means to pay honoraria to the speakers.

20. Beginning in or about July 2013 and continuing through August 2016, Insys compensated Practitioner #1 as a Local, Regional and National speaker for Insys Events. After each Event, the defendant SONIA PALERMO submitted to Insys, via facsimile or email, false or fraudulent sign-in sheets for each Event, along with receipts for food and beverages for the Events and requests for payment for Practitioner #1 as the purported speaker.

21. Between approximately July 2013 and August 2016, the defendant Sonia Palermo arranged approximately 81 Events at which Practitioner #1 purported to be a speaker. In total, between approximately 2013 and 2016, Insys paid Practitioner #1 approximately \$207,840 in speaker fees as part of the scheme.

22. During this same time period, Practitioner #1 prescribed approximately 400 Subsys prescriptions. Between approximately 2013 and August 2016, Medicare paid approximately \$3,658,253 for the Subsys prescriptions written by Practitioner #1.

COUNT ONE
(Conspiracy to Violate the Anti-Kickback Statute)

23. The allegations contained in paragraphs one through 22 are realleged and incorporated as if fully set forth in this paragraph.

24. In or about and between March 2012 and August 2016, both dates being approximate and inclusive, within the Eastern District of New York and elsewhere, the defendant SONIA PALERMO, together with others, did knowingly and willfully conspire to offer and pay kickbacks, directly and indirectly, overtly and covertly, in cash and in kind, to one or more persons to induce such persons to purchase, lease, order, arrange for and recommend purchasing, leasing and ordering a good, facility, service and item for which

payment may be made in whole or in part under a Federal health care program, contrary to Title 42, United States Code, Section 1320a-7b(b)(2)(B).

25. In furtherance of the conspiracy and to effect its objects, within the Eastern District of New York and elsewhere, the defendant SONIA PALERMO, together with others, did commit and cause the commission of, among others, the following:

OVERT ACTS

(a) On or about April 30, 2013, PALERMO organized and attended an Event at a restaurant located in Melville, New York. Practitioner #1 was the purported speaker at the event. Only non-licensed medical staff who were unable to prescribe Subsys attended the Event. After the Event, PALERMO submitted a sign-in sheet to Insys so that Practitioner #1 would receive an honorarium for the Event, even though no licensed healthcare providers were present.

(b) On or about June 10, 2014, PALERMO organized and attended an Event at a restaurant located in Melville, New York, at which Practitioner #1 was the purported speaker. After the Event, PALERMO submitted, by email or facsimile, a false sign-in sheet listing Practitioner #2, a medical doctor practicing on Long Island, New York, whose identity is known to the Grand Jury, as being a licensed healthcare provider in attendance at the Event. However, Practitioner #2 was not in attendance at the Event and PALERMO forged Practitioner #2's signature on the sign-in sheet. On or about June 17, 2014, Insys paid Practitioner #1 \$3,000 for this Event.

(c) On or about August 7, 2014, PALERMO organized and attended an Event at a restaurant located in Syosset, New York. At this Event, Practitioner #1 did not use an Insys slide deck; in fact, Practitioner #1 made no Subsys presentation at all

and merely socialized with other medical providers and staff. On or about August 11, 2014, Insys paid Practitioner #1 \$3,000 for this Event.

(d) On or about September 2, 2014, PALERMO organized and attended an Event at a restaurant located in Syosset, New York. Practitioner #1 was the purported speaker at the Event. After the Event, PALERMO submitted, by email or facsimile, a false sign-in sheet listing Practitioner #3, a medical doctor practicing on Long Island, New York, whose identity is known to the Grand Jury, as being a licensed healthcare provider in attendance at the Event. Practitioner #3 was not in attendance at the Event and PALERMO forged Practitioner #3's signature on the sign-in sheet. On or about September 9, 2014, Insys paid Practitioner #1 \$3,000 for this Event.

(e) On or about May 5, 2015, PALERMO organized and attended an event at a restaurant located in Syosset, New York. Practitioner #1 was the purported speaker at the Event. After the Event, PALERMO submitted, by email or facsimile, a false sign-in sheet listing Practitioner #4, a medical doctor practicing on Long Island, New York, whose identity is known to the Grand Jury, as being a licensed healthcare provider in attendance at the Event. Practitioner #4 was not in attendance at the Event and PALERMO forged Practitioner #4's signature on the sign-in sheet. On or about May 11, 2015, Insys paid Practitioner #1 \$3,000 for this Event.

(Title 18, United States Code, Sections 371 and 3551 et seq.)

COUNT TWO

(Conspiracy to Commit Honest Services Wire Fraud)

26. The allegations contained in paragraphs one through 25 are realleged and incorporated as if fully set forth in this paragraph.

27. In or about and between June 2012 and August 2016, both dates being approximate and inclusive, within the Eastern District of New York and elsewhere, the defendant SONIA PALERMO, together with others, did knowingly and intentionally conspire to devise a scheme and artifice to defraud, and deprive patients of their intangible rights to their doctors' honest services by participating in a scheme to pay bribes and kickbacks to doctors, including Insys Event fees, and for the purpose of executing such scheme or artifice, to transmit and caused to be transmitted by means of wire communication in interstate commerce, writings, signs, signals, pictures and sounds, contrary to Title 18, United States Code, Sections 1343 and 1346.

(Title 18, United States Code, Sections 1349 and 3551 et seq.)

COUNT THREE
(Aggravated Identity Theft)

28. The allegations contained in paragraphs one through 25 are realleged and incorporated as if fully set forth in this paragraph.

29. On or about May 5, 2015, within the Eastern District of New York and elsewhere, the defendant SONIA PALERMO, together with others, during and in relation to the crime charged in Count Two, did knowingly and intentionally possess and use, without lawful authority, means of identification of another person, to wit: Practitioner #4, knowing that the means of identification belonged to such person.

(Title 18, United States Code, Sections 1028A(a)(1), 1028A(b), 1028A(c)(5), 2 and 3551 et seq.)

CRIMINAL FORFEITURE ALLEGATION

30. The United States hereby gives notice to the defendant that, upon her conviction of any of the offenses charged in Counts One and Two, the government will seek forfeiture in accordance with Title 18, United States Code, Section 982(a)(7), which requires any person convicted of a federal health care offense to forfeit property, real or personal, that constitutes, or is derived directly or indirectly from, gross proceeds traceable to the commission of such offenses.

31. If any of the above-described forfeitable property, as a result of any act or omission of the defendant:

- (a) cannot be located upon the exercise of due diligence;
- (b) has been transferred or sold to, or deposited with, a third party;
- (c) has been placed beyond the jurisdiction of the court;
- (d) has been substantially diminished in value; or
- (e) has been commingled with other property which cannot be divided without difficulty;

it is the intent of the United States, pursuant to Title 21, United States Code, Section 853(p), as incorporated by Title 18, United States Code, Section 982(b)(1), to seek forfeiture of any

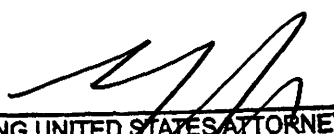
other property of the defendant up to the value of the forfeitable property described in this forfeiture allegation.

(Title 18, United States Code, Sections 982(a)(7) and 982(b)(1); Title 21, United States Code, Section 853(p))

A TRUE BILL


FOREPERSON

RICHARD P. DONOGHUE
UNITED STATES ATTORNEY
EASTERN DISTRICT OF NEW YORK


BY: ACTING UNITED STATES ATTORNEY,
PURSUANT TO 28 C.F.R. O.136

F.#: 2016R01511
FORM DBD-34
JUN. 85

No. _____

UNITED STATES DISTRICT COURT

EASTERN *District of* NEW YORK

CRIMINAL DIVISION

THE UNITED STATES OF AMERICA

vs.

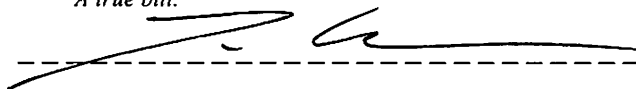
SONIA PALERMO,

Defendant.

INDICTMENT

(T. 18, U.S.C., §§ 371, 981(a)(1)(C), 982(a)(7), 982(b)(1),
1028A(a)(1), 1028A(b), 1028A(c)(5), 1343, 1346, 1349, 2, 3551 et
seq.; T. 21, U.S.C., § 853(p); T. 28, U.S.C., § 2461(c))

A true bill.



Foreperson

Filed in open court this _____ day,

of _____ A.D. 20 _____

Clerk

Bail, \$ _____

Erin E. Argo, Assistant U.S. Attorney (631) 715-7846